

**AMENDMENTS TO THE CLAIMS:**

Replacement Claim Set:

79. (New) An article comprising a kit wherein the kit comprises:
- a) an implantable object comprising a therapeutic substance; and
  - b) a sheath for covering at least part of the implantable object, wherein the sheath comprises a sheath material that prevents:
    - i) the therapeutic substance from significantly diffusing away from the medical device;
    - ii) the therapeutic substance from significantly absorbing into the sheath; or
    - iii) both.
80. (New) An article comprising a kit wherein the kit comprises:
- a) an implantable object comprising a therapeutic substance; and
  - b) a balloon for delivering the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon.
81. (New) An article comprising a kit wherein the kit comprises:
- a) an implantable object comprising a therapeutic substance;
  - b) a balloon for delivering the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon; and

- c) a sheath for covering at least part of the implantable object, wherein the sheath comprises a sheath material that prevents:
    - i) the therapeutic substance from significantly diffusing away from the medical device;
    - ii) the therapeutic substance from significantly absorbing into the sheath;  
or
    - iii) both.
82. (New) An article comprising:
- a) an implantable object comprising a therapeutic substance; and
  - b) a sheath covering at least part of the implantable object, wherein the sheath comprises a sheath material that prevents:
    - i) the therapeutic substance from significantly diffusing away from the medical device;
    - ii) the therapeutic substance from significantly absorbing into the sheath;  
or
    - iii) both.
83. (New) An article comprising:
- a) an implantable object comprising a therapeutic substance; and
  - b) a balloon at least partially disposed within the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon.
84. (New) An article comprising:

- a) an implantable object comprising a therapeutic substance;
  - b) a balloon at least partially disposed within the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon; and
  - c) a sheath covering at least part of the implantable object, wherein the sheath comprises a sheath material that prevents:
    - i) the therapeutic substance from significantly diffusing away from the medical device;
    - ii) the therapeutic substance from significantly absorbing into the sheath;
    - or
    - iii) both.
85. (New) The article of Claim 82 wherein the balloon is integrated with a catheter.
86. (New) The article of Claim 83 wherein the balloon is integrated with a catheter.
87. (New) The article of Claim 84 wherein the balloon is integrated with a catheter.
88. (New) The article of Claim 79 wherein the balloon is integrated with a catheter.
89. (New) The article of Claim 80 wherein the balloon is integrated with a catheter.
90. (New) The article of Claim 81 wherein the balloon is integrated with a catheter.
91. (New) The article of Claim 79-90 wherein the balloon material, sheath material, or both comprise the same or different polymeric material.
92. (New) The article of Claim 91 wherein the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature.

93. (New) The article of Claim 91 wherein the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures.
94. (New) The article of Claim 91 wherein the polymeric material comprises at least one cellulose derivative selected from cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, or their mixtures.
95. (New) The article of Claim 91 wherein the polymeric material comprises a sulfonated or a fluorinated polymeric layer.
96. (New) The article of Claim 91 wherein the polymeric material comprises a carbide or nitride compound.
97. (New) The article of Claim 91 wherein the implantable object comprises a stent.
98. (New) The article of Claim 91 wherein the polymeric material comprises polyolefins, polyurethanes, derivatives of cellulose, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, or their mixtures.
99. (New) The article of Claim 98 wherein polyolefins comprises polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride),

poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), or their mixtures.

100. (New) The article of Claim 98 wherein polyesters comprise poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), or their mixtures.
101. (New) The article of Claim 98 wherein polyamides comprise nylon-6; nylon-6,6; nylon-6,9; nylon-6,10; aromatic nylon; or their mixtures.
102. (New) The article of Claim 91 wherein the polymeric material comprises a predetermined amount of fillers.
103. (New) The article of Claim 91 wherein the balloon materials, sheath materials, or both balloon and sheath materials comprise a layer.
104. (New) The article of Claim 103 wherein the layer comprises a glass material.
105. (New) The article of Claim 103 wherein the layer comprises a metallic material.
106. (New) The article of Claim 103 wherein the layer comprises a therapeutic substance contacting surface.
107. (New) The article of Claim 106 wherein the therapeutic substance contacting surface contacts a coating comprising a main-group-element oxide.
108. (New) The article of Claim 107 wherein the main-group-element oxide comprises a silicon oxide, metal oxide, or a mixture of a silicon and a metal oxide.
109. (New) The article of Claim 80, 81, 83, 84, or 85-90 wherein the balloon is defined by a balloon wall.

110. (New) The article of Claim 109 wherein the balloon wall has an oxygen transmission rate of not more than about 200 cc/100 in<sup>2</sup>, for 1 mil per 24 hrs, at 73° F, 75% relative humidity, and 1 atm.
111. (New) The article of Claim 109 wherein the balloon wall has a water vapor transmission rate of not more than 20 gm/100 in<sup>2</sup> for 1 mil per 24 hrs, at 100° F (38° C), 90% relative humidity, and 1 atm (760 mm Hg).
112. (New) The article of Claim 111 wherein the balloon wall has an oxygen transmission rate of not more than about 200 cc/100 in<sup>2</sup>, for 1 mil per 24 hrs, at 73° F, 75% relative humidity, and 1 atm.
113. (New) The article of Claim 79, 81, 82, 84, or 85-90 wherein the sheath is defined by a sheath wall.
114. (New) The article of Claim 113 wherein the polymeric material has a water vapor transmission rate of not more than 20 gm/100 in<sup>2</sup> for 1 mil per 24 hrs, at 100° F, 90% relative humidity, and 1 atm.
115. (New) The article of Claim 113 wherein the polymeric material has a water vapor transmission rate of not more than 20 gm/100 in<sup>2</sup> for 1 mil per 24 hrs, at 100° F, 90% relative humidity, and 1 atm.
116. (New) The article of Claim 115 wherein the polymeric material has an oxygen transmission rate of not more than about 200 cc/100 in<sup>2</sup>, for 1 mil per 24 hrs, at 73° F, 75% relative humidity, and 1 atm.
117. (New) The article of Claim 81, 84, 85-90 wherein the balloon is defined by a balloon wall and the sheath is defined by a sheath wall.

118. (New) The article of Claim 117 wherein the balloon, sheath, or both have a water vapor transmission rate of not more than  $20 \text{ gm}/100 \text{ in}^2$  for 1 mil per 24 hrs, at  $100^\circ \text{ F}$ , 90% relative humidity, and 1 atm.
119. (New) The article of Claim 118 wherein the balloon, sheath, or both have an oxygen transmission rate of not more than about  $200 \text{ cc}/100 \text{ in}^2$ , for 1 mil per 24 hrs, at  $73^\circ \text{ F}$ , 75% relative humidity, and 1 atm.
120. (New) The article of Claim 119 wherein the balloon, sheath, or both have a water vapor transmission rate of not more than  $20 \text{ gm}/100 \text{ in}^2$  for 1 mil per 24 hrs, at  $100^\circ \text{ F}$ , 90% relative humidity, and 1 atm.
121. (New) The article of Claim 109 wherein the balloon is capable of dilating by inflating from a collapsed configuration to an expanded configuration and selectively constricting by deflating from the expanded configuration to the collapsed configuration.
122. (New) The article of Claim 121 wherein the balloon material is deposited on at least a portion of the balloon in a layer.
123. (New) The article of Claim 91 wherein the sheath material is deposited on at least a portion of the inner surface of the sheath in a layer.
124. (New) The article of Claim 113 wherein the implantable object is disposed within the sheath for transportation or storage.
125. (New) The article of Claim 114 wherein the implantable object is disposed within the sheath for transportation or storage.
126. (New) The article of Claim 115 wherein the implantable object is disposed within the sheath for transportation or storage.

127. (New) The article of Claim 116 wherein the implantable object is disposed within the sheath for transportation or storage.
128. (New) The article of Claim 91 wherein the material is selected from:
- a) polyurethane having a glass transition temperature above a storage temperature;
  - b) polyurethane having a non-polar soft segment wherein the non-polar soft segment is at least one of hydrocarbons, silicones, fluorosilicones, or mixtures thereof;
  - c) at least one cellulose derivative selected from cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, or mixtures thereof;
  - d) sulfonated polymers;
  - e) fluorinated polymers;
  - f) carbide compounds;
  - g) nitride compounds;
  - h) a polyolefin that is at least one of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), or mixtures thereof;
  - i) a polyester that is at least one of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), or mixtures thereof;
  - j) a polyamide that is at least one of nylon-6; nylon-6,6; nylon-6,9; nylon-6,10; aromatic nylon; or mixtures thereof; and
  - k) mixtures of a)-j).



129. (New) The article of Claim 79-90 wherein the article is a medical device.
130. (New) A method of making the article of Claim 129 comprising
- a) covering at least part of the implantable object with a sheath wherein the sheath comprises a sheath material that prevents:
    - i) the therapeutic substance from significantly diffusing away from the medical device;
    - ii) the therapeutic substance from significantly absorbing into the sheath;  
or
    - iii) both;
  - b) alternatively, supplying
    - i) an implantable object comprising a therapeutic substance; and
    - ii) a balloon for delivering the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon;
  - c) or, alternatively,
    - i) covering at least part of the implantable object with a sheath wherein the sheath comprises a sheath material that prevents:
      - the therapeutic substance from significantly diffusing away from the medical device;
      - the therapeutic substance from significantly absorbing into the sheath; or
      - both; and

- ii) at least partially inserting the balloon for delivering the implantable object into the implantable object, wherein the balloon comprises a balloon material that prevents the therapeutic substance from significantly absorbing into the balloon.
131. (New) The method of Claim 130 wherein the balloon is integrated with a catheter.
132. (New) The method of Claim 130 wherein the balloon material, sheath material, or both comprise the same or different polymeric material.
133. (New) The method of Claim 132 wherein the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature.
134. (New) The method of Claim 132 wherein the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures.
135. (New) The method of Claim 132 wherein the polymeric material comprises at least one cellulose derivative selected from cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, or their mixtures.
136. (New) The method of Claim 132 wherein the polymeric material comprises a sulfonated or a fluorinated polymeric layer.
137. (New) The method of Claim 132 wherein the polymeric material comprises a carbide or nitride compound.
138. (New) The method of Claim 132 wherein the implantable object comprises a stent.